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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

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DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/917,176

Applicant(s)
Bournsnel

Examiner
Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 26, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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The request filed on June 21, 1999 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/604,164 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 11, 12, 14-19, and claims 20-29 have been added by the amendment dated June 21, 1999.

Claim 10 has been amended by the supplemental amendment filed on July 2, 1999.

Claims 1, 3, 5-12, and 14-29 are pending

The examiner notes that during the initial examination of this application, there was no restriction requirement even though a search of prior art for all originally filed claims was conducted by the examiner. However, upon further updated searches in response to applicant's amendments to the originally filed claims, and upon a further consideration of all pertinent art, all presently pending claims are subjected to a restriction requirement as set forth below. A restriction is now required because it would be burdensome for the examiner to search and consider for patentability of all presently pending claims.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to mutant viruses and a process of using the mutant viruses of claim 1 encoding a heterologous antigen as a vaccine to treat a subject, classified in class 435, subclass 320.1, and class 435, subclass 325, class 424, subclass 93.2.
- II. Claim 13, drawn to a method of growing or expanding cytotoxic T cells by using the mutant viruses of claim 1, classifiable in class 435, subclass 325.
- III. Claims 14, drawn to *in vivo* therapy method of using the mutant viruses encoding a corrective gene for the purpose of therapy or prophylactic corrective therapy, classified in class 424, subclass 93.2.
- IV. Claims 12, 15-19, drawn to process of using the mutant viruses for an *ex vivo* gene therapy wherein *ex vivo* cells including those of tumor cells containing

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the mutant viruses are employed in the *ex vivo* gene therapy, classified in class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Invention II, III, and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the mutant viruses of Invention I are not limited in the processes cited in inventions II to III and can be used for production of immunodulatory molecules *in vitro* or expansion of genetically modified cells *in vitro*. Thus, it would be a serious burden for the examiner to search all claims of Inventions I and II.

Methods of Inventions II and III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions II and III are directed to different goals and comprises materially distinct steps and generate different functions and effects, and thus, are not required for use together. Thus, it would be burdensome for the examiner to examine all prior art pertinent to patentably distinct inventions II and III.

Claims 7 is generic to a plurality of disclosed patentably distinct species comprising an coding sequence of a protein essential for the production of virus particles:

gH, gB, gD, gL, ICP4, ICP8, and ICP27.

Should Group I be elected, Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species as listed above (claim 7), even though this requirement is traversed.

Claims 8 and 9 are generic to a plurality of disclosed patentably distinct species comprising an coding sequence of a protein essential for the production of virus particles:

GM-CSF, O:-2, O:-12, PX40, PX40L (gp34), and CD40L.

Should Group I be elected, Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species as listed above (claims 8 and 9), even though this requirement is

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traversed.

Should Group I be elected or should the claims be amended to claim multiple distinct species as listed above, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

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Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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A handwritten signature in black ink, consisting of a stylized 'D' followed by a horizontal line and a small flourish.

DAVE T. NGUYEN
PRIMARY EXAMINER